**Pharyngeal Electrical stimulation for Acute Stroke dysphagia Trial (PhEAST)**

**Aphasia Friendly Participant Information Sheet and Consent Form**

(Final version 2.0: 09/08/2022)

**IRAS Project ID: 304658**

**Name of researcher:**

**Name of participant:**

|  |
| --- |
| **Pharyngeal Electrical stimulation for Acute**  **Stroke dysphagia Trial (PhEAST)**  **What is this about?**  We want to know if you would like to **take part** in a **research** **study** called PhEAST.    The study will test if giving **electric stimulation** in a **feeding tube** can help you to **swallow better**.      We will **tell you about the study** and **answer** any **questions** you may have.  Description: C:\Users\SRN\Dropbox\Artwork Stroke\Consent Form Artwork\1 Hospital.jpg  If you are **not well enough** we will try to ask your **family** or **friend**.  C:\Users\SRN\Dropbox\Artwork Stroke\3 concentrate (hand) 2 .jpg    It is **your choice** to take part in the study.  Description: C:\Users\SRN\Dropbox\Artwork Stroke\Consent Form Artwork\1 Hospital.jpg  You **don’t have to** take part if you don’t want to. |
| **Why** are we asking you to **take part** in the study?  You have had a **stroke** in your **brain**.  C:\Users\SRN\Dropbox\Artwork Stroke\Consent Form Artwork\1 Hospital.jpg      The stroke has caused **difficulty swallowing**.  C:\Users\SRN\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.IE5\WYE21IW1\dglxasset[1].aspxC:\Users\SRN\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.IE5\WYE21IW1\dglxasset[1].aspx  **If you take part:**  You will receive all the **care and treatments** you would **normally receive**.    Description: C:\Users\SRN\Dropbox\Artwork Stroke\Consent Form Artwork\1 Hospital.jpgDescription: C:\Users\SRN\Dropbox\Artwork Stroke\Consent Form Artwork\1 Hospital.jpg |
| A nurse or doctor will put a **tube** in your **nose for feeding**. You may need an **X-RAY** to confirm the tube is in the right place.  X-rays are a form of ionising **radiation** and are used to create images of your body. The risk of exposure to radiation is that you may develop cancer some years in the future.  1 in 2 people in the UK will develop cancer at some point in their lifetime. Taking part in the study will **increase the chance** of this happening to you by **only a very small amount.**      **Half** the people in this study will get a **small electrical current** applied to the tube at the **back of the throat**.  Diagram  Description automatically generated  This is decided by **chance** – you don’t know which one you will get. The **computer decides.**  This is like **flipping a coin.**  Description: C:\Users\SRN\Dropbox\Artwork Stroke\Consent Form Artwork\1 Hospital.jpg    You **may** or **may not feel** the electrical stimulation.  The treatment will last for:    **10 minutes**      every day for **6 days**  A picture containing text  Description automatically generated    The **researcher** will **collect information** about your **swallowing**, **health** and **cognition** over **6 days**    A picture containing text  Description automatically generated  And also at **3 months** and **6 months**  Graphical user interface, application, Word  Description automatically generated |
| And also at **1 year**  **Table  Description automatically generated**  **Risks**  The risk is **no greater** than for **standard care** with a **nasogastric feeding tube**. |
| **Follow-up:**  A **researcher** will **call** you to see **how you are**, if you have had any **problems** and how well you have **recovered**.    Description: C:\Users\SRN\Dropbox\Artwork Stroke\Consent Form Artwork\1 Hospital.jpg  If you are **not well enough** to talk we will try to ask your **family**, **friend** or **GP**.  C:\Users\SRN\Dropbox\Artwork Stroke\3 concentrate (hand) 2 .jpg  They will **call** you:  **3 months** and **6 months** after your stroke  Graphical user interface, application, Word  Description automatically generated  They will also call you **1 year** after your stroke  Table  Description automatically generated |
| **During the study:**  If you have any **questions** then please ask.    You may decide you **do not want to take part at any time**.  Description: C:\Users\SRN\Dropbox\Artwork Stroke\Consent Form Artwork\1 Hospital.jpg  This will **not affect your care** now or in the future.  Description: C:\Users\SRN\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.IE5\KW8IYCP4\MC900432537[3].png C:\Users\SRN\Dropbox\Artwork Stroke\2 eating.jpg  All the **information** we hold about you will be kept in the strictest **confidence**.    What you say to us is **confidential.**  **However, if** **you say anything** to us which we feel puts **you or anyone else at any risk**, we may need to **report this** to the appropriate persons. |

**Pharyngeal Electrical stimulation for Acute Stroke dysphagia Trial (PhEAST)**

**Aphasia Friendly Participant Information Sheet and Consent Form**

I **confirm** that I have been given a **copy** of the **Patient Information Sheet** (Version xx dated xx/xx/xxxx) and I agree that I:

* Yes, I will **take part** in the **PhEAST** study

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* For my **medical records to be accessed** by the study team

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* To be **followed up at 3 months** and **6 months**

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* To be **followed up at 1 year**

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* For my **GP to be informed** of my participation in the study.



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* For **my contact details to be collected and used** for the purpose of the study

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* For my **anonymised confidential data** to be used in **further research** analysis about stroke.

A close-up of a computer

Description automatically generated with low confidence

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* I understand that I am **free to withdraw** from the study **at any point** without giving a reason.

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Description automatically generated 

**Patient consent – to be completed if participant has capacity to consent**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

# Name of Participant Date Signature

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Name of Person taking consent Date Signature

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Name of Witness if participant Date Signature

unable to sign physically

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Role of Witness if participant

unable to sign physically

This sheet has been designed using resources from [https://www.aphasiatrials.org/templates-for-accessible-information-sheets-and-consent-forms/](about:blank)